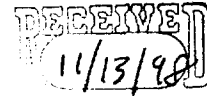




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November 15, 1998



The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Standard Process offers many products that will help support your immune system from the stresses of modern life and the changing seasons.*
- (2) The main purpose of these aqueous tissue extracts is to support the patients' hormone-dependent tissue functions until the tissue is able to do so itself.*

These statements are made for a dietary supplement containing calcium lactate, magnesium citrate, bovine thymus Cytosol Extract, carrot powder, ribonucleic acid, bone meal, defatted wheat germ, vacuum dried bovine adrenal, vacuum dried alfalfa juice, nutritional yeast, oat flour, vacuum dried buckwheat juice and seed, alfalfa meal, vacuum dried bovine kidney, veal bone meal, veal bone PMG Extract, mushroom powder, ascorbic acid, peanut bran, vitamin A esters, soy bean lecithin, mixed tocopherols, and carrot oil. The name of the product is Congaplex®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.



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STANDARD PROCESS INC. • 1200 WEST ROYAL LEE DRIVE • PALMYRA, WI 53156 • 414-495-2122 • FAX 414-495-2512 • 1-800-848-5061

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